

Message

From: Reynolds, Alan [Reynolds.Alan@epa.gov]
Sent: 3/8/2021 6:15:34 PM
To: Bohnenblust, Eric [Bohnenblust.Eric@epa.gov]
Subject: FW: Time Sensitive: 93167-EUP-2
Attachments: 20210302104914592.pdf

Importance: High

Eric-

We got this inquiry from Region 4 with respect to Oxitec importing OX 5034 mosquitoes. I think most of the issues are a lack of understanding of the label by Region 4. Can you look into this so we can respond?

Thanks, Alan

From: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>
Sent: Monday, March 8, 2021 12:29 PM
To: Reynolds, Alan <Reynolds.Alan@epa.gov>
Cc: Bauman, Michael <bauman.michael@epa.gov>; Ho, Kanoelehua <ho.kanoelehua@epa.gov>; Ortiz, Deborah <ortiz.deborah@epa.gov>
Subject: Time Sensitive: 93167-EUP-2
Importance: High

Hi Alan,

A company is imported a Experimental Use product (93167-EUP-2) into a Region 4 Port of Entry.

The following discrepancies were found:

1. The ingredient statement doesn't appear correct;
2. The label lacks warning or caution statements;
3. Can this EUP label include the stamp "Accepted" on the label that is imported?

A colleague pointed out to me that there are some proposed label changes in Documentum from a December submission, but nothing that appears finalized.

Can you provide guidance if the attached import label is problematic or if the issues identified are acceptable?

Thank you,

Kimberly Tomczak, Life Scientist
US Environmental Protection Agency, Region 4
Pesticide Enforcement Section
61 Forsyth St. SW Atlanta, GA 30303
Phone: 404.562.8987
Email: Tomczak.kimberly@epa.gov

From: Bauman, Michael <bauman.michael@epa.gov>
Sent: Monday, March 8, 2021 12:05 PM
To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>; Ortiz, Deborah <ortiz.deborah@epa.gov>

Cc: Ho, Kanoelehua <ho.kanoelehua@epa.gov>
Subject: RE: Job 7482, MAWB 001-4748-4846, BUP35341091

Hi Deborah/Kim,

They provided a copy of the EPA-accepted EUP label. You may just want to reach out to the PM about this product for a 15 min call. They've got some proposed label changes in Documentum from a December submission, but nothing that appears finalized.

The label being presented may represent exactly what the EPA has already accepted for what this product is (mosquito eggs) and there may be reasons, already discussed within OPP, for the label questions about the ingredient statement and precautionary language discussed below - in which case it may be able to be released.

PM is:
Reynolds, Alan 703-605-0515
Biologicals & Pollution Prevention Division, PM Team 94

You can look up the PM Team online to contact his branch manager if he's out of the office or doesn't respond.

Regards,
Michael

Tel: 404-562-8962 | Email: bauman.michael@epa.gov

From: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>
Sent: Monday, March 8, 2021 10:39 AM
To: Ortiz, Deborah <ortiz.deborah@epa.gov>; Bauman, Michael <bauman.michael@epa.gov>
Cc: Ho, Kanoelehua <ho.kanoelehua@epa.gov>
Subject: RE: Job 7482, MAWB 001-4748-4846, BUP35341091

Hi Deborah,

We need to have them verify the label they provided is the label that is affixed to the product being imported.

Specifically: Have the importer review the label and any labeling (e.g. manuals, booklets, inserts, etc.) provided to ensure that it is a true and complete copy of what is affixed to and accompanying the product. If the documents are complete, have the importer provide a signed letter on company letterhead stating this. If in response the importer provides additional documentation, please have the importer also provide a signed letter on company letterhead stating the date the new documents were provided and a statement expressing that what has been provided represents a true and complete copy of what is affixed to and accompanying each product container (e.g. bottle, jug, IBC, sack, drum, bag, tank, etc.).

Can you redraft the email with that language?

I will bring this topic up during the imports meeting.

From: Ortiz, Deborah <ortiz.deborah@epa.gov>
Sent: Monday, March 8, 2021 9:18 AM
To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>; Bauman, Michael <bauman.michael@epa.gov>
Cc: Ho, Kanoelehua <ho.kanoelehua@epa.gov>
Subject: RE: Job 7482, MAWB 001-4748-4846, BUP35341091

Hi Kimberly (and team) how about this email to the company?

For entry number BUP-35341091, please address the following point(s) immediately for the review of the entry:

- The label fails to include a full ingredient statement
- The label lacks warning or caution statements

Below is a link for the labeling requirements of pesticides shipped or used under an experimental use permit.

<https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit#labeling>

Please review the label and any labeling (e.g. manuals, booklets, inserts, etc.) provided to ensure that it is a true and complete copy of what is affixed to and accompanying the product. If the documents are complete, please provide a signed letter on company letterhead stating this. If in response requires additional documentation, please also provide a signed letter on company letterhead stating the date the new documents were provided and a statement expressing that what has been provided represents a is a true and complete copy of what is affixed to and accompanying each product container (e.g. bottle, jug, IBC, sack, drum, bag, tank, etc.).

Regards,
Deborah

From: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>
Sent: Monday, March 8, 2021 6:33 AM
To: Bauman, Michael <bauman.michael@epa.gov>; Ortiz, Deborah <ortiz.deborah@epa.gov>
Cc: Ho, Kanoelehua <ho.kanoelehua@epa.gov>
Subject: RE: Job 7482, MAWB 001-4748-4846, BUP35341091

Thanks for follow up on this Michael. I didn't see Deborah's email until now.

From: Bauman, Michael <bauman.michael@epa.gov>
Sent: Friday, March 5, 2021 3:45 PM
To: Ortiz, Deborah <ortiz.deborah@epa.gov>; Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>
Cc: Ho, Kanoelehua <ho.kanoelehua@epa.gov>
Subject: RE: Job 7482, MAWB 001-4748-4846, BUP35341091

Deborah,

Looks like Kim has left and I'm already in the Correspondence Document; the bullets you provided don't have a requested action for the importer or broker – I adapted some other language in the document to work for an NOA – you may need to tweak it some more so that it works for this entry; please send around again so Kim can see it on Monday:

Have the importer review the label and any labeling (e.g. manuals, booklets, inserts, etc.) provided to ensure that it is a true and complete copy of what is affixed to and accompanying the product. If the documents are complete, have the importer provide a signed letter on company letterhead stating this. If in response the importer provides additional documentation, please have the importer also provide a signed letter on company letterhead stating the date the new documents were provided and a statement expressing that what has been provided represents a is a true and complete copy of what is affixed to and accompanying each product container (e.g. bottle, jug, IBC, sack, drum, bag, tank, etc.).

Regards,
Michael

Tel: 404-562-8962 | Email: bauman.michael@epa.gov

From: Ortiz, Deborah <ortiz.deborah@epa.gov>
Sent: Friday, March 5, 2021 2:00 PM
To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>
Cc: Bauman, Michael <bauman.michael@epa.gov>; Ho, Kanoelehua <ho.kanoelehua@epa.gov>
Subject: RE: Job 7482, MAWB 001-4748-4846, BUP35341091

Hi Kimberly,

I've looked their "label" over a few times and you are correct. (Although the tone of their email is uncomfortable). The Sample Email to send them is below.

Good Afternoon,

For entry number BUP-35341091, please address the following point(s) immediately for the review of the entry:

- The label fails to include a full ingredient statement
- The label lacks warning or caution statements

Below is a link for the labeling requirements of pesticides shipped or used under an experimental use permit.
<https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit#labeling>

The cargo of the entry should remain held intact until the abovementioned issues have been resolved or additional information is provided. If you have questions or would like additional information regarding this shipment, I may be contacted by phone or email (see below). Please use reply all to confirm the requested items have been addressed.

Regards,

Deborah

Tel: 404-562-8230 · Email: ortiz.deborah@epa.gov

Physical Scientist · Pesticides Enforcement Section

Enforcement & Compliance Assurance Division · U.S. EPA Region 4

From: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>
Sent: Friday, March 5, 2021 12:56 PM
To: Ortiz, Deborah <ortiz.deborah@epa.gov>
Cc: Bauman, Michael <bauman.michael@epa.gov>; Ho, Kanoelehua <ho.kanoelehua@epa.gov>
Subject: RE: Job 7482, MAWB 001-4748-4846, BUP35341091

Hi Deborah,

The label doesn't include a full ingredient statement. Also, is there a warning or caution statements? All I see is "keep out of reach of children". I'm not sure that is sufficient.

<https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit#labeling>

From: Ortiz, Deborah <ortiz.deborah@epa.gov>
Sent: Friday, March 5, 2021 12:00 PM
To: Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>
Subject: FW: Job 7482, MAWB 001-4748-4846, BUP35341091

Hi Kimberly,

Here is this NOA starting with BUP with their revised label. Just waiting on your approval to release.

Thanks,
Deborah

From: Morency, Felder <fmorency@worldcustomsbrokerage.com>
Sent: Friday, March 5, 2021 11:37 AM
To: Ortiz, Deborah <ortiz.deborah@epa.gov>; Bauman, Michael <bauman.michael@epa.gov>
Cc: Torregrossa, Andrea <achlupsa@worldcustomsbrokerage.com>; Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>; Ho, Kanoelehua <ho.kanoelehua@epa.gov>; Bauman, Michael <bauman.michael@epa.gov>; Diaz, Annette <adiaz@worldcustomsbrokerage.com>
Subject: FW: Job 7482, MAWB 001-4748-4846, BUP35341091

Good morning all,

Please provide an update with the EPA permit. We have started this journey in Feb. 25th. The last respond that I received from you was on March 2nd. The EPA permit is very important for this shipment. Please let us know when we are able to move forward with the shipment.

Felder

From: Morency, Felder
Sent: Thursday, March 4, 2021 7:21 AM
To: 'Ortiz, Deborah' <ortiz.deborah@epa.gov>; 'Bauman, Michael' <bauman.michael@epa.gov>
Cc: Torregrossa, Andrea <achlupsa@worldcustomsbrokerage.com>; 'Tomczak, Kimberly' <Tomczak.Kimberly@epa.gov>; 'Ho, Kanoelehua' <ho.kanoelehua@epa.gov>; 'Bauman, Michael' <bauman.michael@epa.gov>; Diaz, Annette <adiaz@worldcustomsbrokerage.com>
Subject: RE: Job 7482, MAWB 001-4748-4846, BUP35341091

Good morning Deborah,

Please provide an update in regards to the EPA permit.

From: Morency, Felder
Sent: Tuesday, March 2, 2021 10:52 AM
To: 'Ortiz, Deborah' <ortiz.deborah@epa.gov>; Bauman, Michael <bauman.michael@epa.gov>
Cc: Torregrossa, Andrea <achlupsa@worldcustomsbrokerage.com>; Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>; Ho, Kanoelehua <ho.kanoelehua@epa.gov>; Bauman, Michael <bauman.michael@epa.gov>; Diaz, Annette <adiaz@worldcustomsbrokerage.com>
Subject: RE: Job 7482, MAWB 001-4748-4846, BUP35341091

Hello Deborah,

Please review the attached documents that has the establishment number.

From: Ortiz, Deborah <ortiz.deborah@epa.gov>

Sent: Tuesday, March 2, 2021 9:39 AM

To: Morency, Felder <fmorency@worldcustomsbrokerage.com>; Bauman, Michael <bauman.michael@epa.gov>

Cc: Torregrossa, Andrea <achlupsa@worldcustomsbrokerage.com>; Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>;
Ho, Kanoelehua <ho.kanoelehua@epa.gov>; Bauman, Michael <bauman.michael@epa.gov>; Diaz, Annette
<adiaz@worldcustomsbrokerage.com>

Subject: RE: Job 7482, MAWB 001-4748-4846, BUP35341091

CAUTION: This email originated from outside of the organization. DO NOT CLICK links or open attachments unless you recognize the sender and know the content is safe.

Good Morning,

For entry number BUP-3534109, please address the following point(s) immediately for the review of the entry:

- This entry lacks an adequate label with the EPA producer Establishment Number.

The cargo of the entry should remain held intact until the abovementioned issues have been resolved or additional information is provided. If you have questions or would like additional information regarding this shipment, I may be contacted by phone or email (see below). Please use reply all to confirm the requested items have been addressed.

Regards,
Deborah

Tel: 404-562-8230 · Email: ortiz.deborah@epa.gov

Physical Scientist · Pesticides Enforcement Section

Enforcement & Compliance Assurance Division · U.S. EPA Region 4

From: Morency, Felder <fmorency@worldcustomsbrokerage.com>

Sent: Tuesday, March 2, 2021 8:25 AM

To: Ortiz, Deborah <ortiz.deborah@epa.gov>; Bauman, Michael <bauman.michael@epa.gov>

Cc: Torregrossa, Andrea <achlupsa@worldcustomsbrokerage.com>; Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>;
Ho, Kanoelehua <ho.kanoelehua@epa.gov>; Bauman, Michael <bauman.michael@epa.gov>; Diaz, Annette
<adiaz@worldcustomsbrokerage.com>

Subject: RE: Job 7482, MAWB 001-4748-4846, BUP3534109

Good morning Deborah,

Thank you! We will be waiting for your response.

From: Ortiz, Deborah <ortiz.deborah@epa.gov>

Sent: Monday, March 1, 2021 4:34 PM

To: Morency, Felder <fmorency@worldcustomsbrokerage.com>; Bauman, Michael <bauman.michael@epa.gov>

Cc: Torregrossa, Andrea <achlupsa@worldcustomsbrokerage.com>; Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>;
Ho, Kanoelehua <ho.kanoelehua@epa.gov>; Bauman, Michael <bauman.michael@epa.gov>
Subject: RE: Job 7482, MAWB 001-4748-4846, BUP3534109

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Good Afternoon/Morning,

Thank you for your NOA Entry BUP-3534109. We are currently reviewing the documents and will get back to you shortly with either a determination, or a request for more information.

Regards,
Deborah

Tel: 404-562-8230 · Email: ortiz.deborah@epa.gov
Physical Scientist · Pesticides Enforcement Section
Enforcement & Compliance Assurance Division · U.S. EPA Region 4

From: Morency, Felder <fmorency@worldcustomsbrokerage.com>
Sent: Monday, March 1, 2021 1:37 PM
To: Ortiz, Deborah <ortiz.deborah@epa.gov>; Bauman, Michael <bauman.michael@epa.gov>
Cc: Torregrossa, Andrea <achlupsa@worldcustomsbrokerage.com>; Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>;
Ho, Kanoelehua <ho.kanoelehua@epa.gov>; Bauman, Michael <bauman.michael@epa.gov>
Subject: RE: Job 7482, MAWB 001-4748-4846, BUP3534109

Good afternoon Ms. Ortiz

Please provide an update with documents as the shipment is scheduled to arrive tomorrow.

From: Ortiz, Deborah <ortiz.deborah@epa.gov>
Sent: Friday, February 26, 2021 3:17 PM
To: Morency, Felder <fmorency@worldcustomsbrokerage.com>; Bauman, Michael <bauman.michael@epa.gov>
Cc: Torregrossa, Andrea <achlupsa@worldcustomsbrokerage.com>; Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>;
Ho, Kanoelehua <ho.kanoelehua@epa.gov>; Bauman, Michael <bauman.michael@epa.gov>
Subject: RE: Job 7482, MAWB 001-4748-4846, BUP3534109

CAUTION: This email originated from outside of the organization. DO NOT CLICK links or open attachments unless you recognize the sender and know the content is safe.

Good Afternoon,

Thank you for your NOA Entry BUP-3534109. We are currently reviewing the documents and will get back to you shortly with either a determination or request for more information.

Regards,
Deborah

Tel: 404-562-8230 · Email: ortiz.deborah@epa.gov
Physical Scientist · Pesticides Enforcement Section
Enforcement & Compliance Assurance Division · U.S. EPA Region 4

From: Morency, Felder <fmorency@worldcustomsbrokerage.com>

Sent: Friday, February 26, 2021 12:40 PM

To: Bauman, Michael <bauman.michael@epa.gov>; Tomczak, Kimberly <Tomczak.Kimberly@epa.gov>; Ortiz, Deborah <ortiz.deborah@epa.gov>; Ho, Kanoelehua <ho.kanoelehua@epa.gov>

Cc: Torregrossa, Andrea <achlupsa@worldcustomsbrokerage.com>

Subject: FW: Job 7482, MAWB 001-4748-4846, BUP3534109

Good afternoon,

Please provide an update with the above EPA documents for a shipment of Mosquito eggs.

From: Morency, Felder

Sent: Thursday, February 25, 2021 12:23 PM

To: 'Tomcza' Bauman.michael@epa.gov' <Bauman.michael@epa.gov>; k.kimberly@epa.gov' <Tomczak.kimberly@epa.gov>; 'Ortiz.deborah@epa.gov' <Ortiz.deborah@epa.gov>; 'Ho.kanoelehua@epa.gov' <Ho.kanoelehua@epa.gov>

Cc: Torregrossa, Andrea <achlupsa@worldcustomsbrokerage.com>

Subject: Job 7482, MAWB 001-4748-4846, BUP3534109-1

Good morning,

Please review the attached notice of arrival for an EPA shipment that consist of mosquito eggs (Aedes Aegypti) eggs OX5034. The shipment is schedule to arrive March 2 in the port of Miami (5206).

Please confirm if we need to send you the original notice of arrival once the shipment has cleared all agencies that are involved. If so, provide your mailing address.

Thank you!

To ensure that immediate attention is given to your correspondence please respond to this e-mail by replying to all.

Should you have any further questions or concerns, please do not hesitate to contact us at 800.221.6600 EXT 1214007

As always, thank you for choosing World Customs Brokerage,

Best Regards,

Felder Morency
World Customs Brokerage Inc
Regulatory Broker

4429-4439 NW 97th Avenue
Miami, FL 33178

Tel: +1-800-221-6600 x 1214007

www.worldcourier.com

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